UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,131	03/15/2002	Gerald Walter	VOSS-P01-001	6180

28120 7590 02/12/2004

ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,131	WALTER ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *3,6-9 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,10-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *See page 4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 10/24/03 is acknowledged and entered. Claim 14 is amended by the amendment. Claims 21-23 are added by the amendment.

2. Claims 1-23 are pending.

Election/Restrictions

3. It is noted that the newly added Claims 21-23 would be joined with Group I (Claims 1-17, and 19-20). Thus, Group I is Claims 1-17, and 19-23.

4. Applicant's election with traverse of Group I (Claims 1-17, and 19-23) in Paper No. 10/24/03 is acknowledged.

The traversal is on the ground(s) that because claim 18 is dependent on claim 1 it shared a common technical feature and it would link claim 18 to the generic claim 1.

This is not found persuasive because the claimed method of claim 1 is a common assay method and would not define a contribution as a whole, makes over the prior art and therefore would not be considered a "special technical feature". Although in general claims have some form of dependency, the dependency itself does not define the claim as a linking claim. Claim 18 is directed to a method of production a pharmaceutical composition and Claim 1 is direct to an assay method. Therefore, Group II is not rejoined with Group I.

The requirement is still deemed proper and is therefore made **FINAL**.

5. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10/24/03.

6. Applicant's species election with traverse in Paper No. 10/24/03 is acknowledged. Applicant has elected the following species for the elected invention (Claims 1-17 and 19-23):

a. First molecule: an organic molecule (an antibody or a fragment or a derivative thereof).

b. Second molecule: an organic molecule (a CDNA expression product or a fragment thereof).

c. Type of attachment to magnetic particle: an affinity tag (His-tag).

d. Type of "immunological" means: ELISA.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement is still deemed proper and is therefore made **FINAL**.

7. Claims 3, 6-9, and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a ***nonelected species***, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10/24/03.

Priority

8. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

9. The information disclosure statements (IDS) submitted by applicant filed on 1/7/2002 and 3/12/2002 are acknowledged and considered.

10. Claims 1-2, 4-5, 10-17, and 19 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-2, 4-5, 10-17, and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claim 1 briefly recites a method for the selection of at least one member of a number of specifically interacting molecules from libraries. The method steps comprises a)

contacting a first molecule with a second molecule affixed to a magnetic particle; b) subjecting the product obtained in step (a) to at least one washing step; c) determining whether a specific interaction between said first and second molecule had occurred; and d) providing the first and/or second molecule selected by steps (a) to (c).

The specification disclosure does not sufficiently teach the method for the selection of at least one member of a number of specifically interacting molecules from libraries.

The specification description and examples are directed to a method of detecting ligand-binding activity (e.g. antibody-ligand or protein-protein interaction) with known magnetic particles such as commercial beads (e.g. Dynabeads). The specification examples are drawn to an ELISA method for detecting antibody-ligand interaction with magnetic particle phage (Example 10) and a method of detecting protein-protein interaction with magnetic particle (Example 13). These methods clearly does not provide an adequate representation regarding the for the selection of at least one member of a number of specifically interacting molecules from libraries. Thus the specification does not teach the method for the selection of at least one member of a number of specifically interacting molecules from libraries.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of the method of detecting ligand-binding activity (e.g. antibody-ligand or protein-protein interaction) with known magnetic particles such as commercial beads (e.g. Dynabeads) disclosed by the specification example, the skilled artisan cannot envision the method for the selection of at least one member of a number of specifically interacting molecules from libraries. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making and/or isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the claimed method for the selection of at least one member of a number of specifically interacting molecules from libraries. The specification does not teach the method for the selection of at least one member of a number of specifically interacting molecules from libraries. Therefore, only the method of detecting ligand-binding activity (e.g. antibody-

ligand or protein-protein interaction) with known magnetic particles such as commercial beads (e.g. Dynabeads), but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-2, 4-5, 10-17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. It is unclear as to the correlation of the term "libraries" of claim 1 with regard to the claimed method steps since the claimed method steps refers to the method of detecting interaction between the first and second molecules.

b. The method step (d) of claim 1 is vague and indefinite because it is unclear as to the "providing the first and/or second molecule selected by steps (a) to (c)" when the result of steps (a) to (c) is the product of the "compound/composition" of the interaction of the first and second molecules.

c. The second limitation of "*and, if said specific interaction had occurred*" of step (c) of claim 1 is vague and indefinite because it is a reiteration of the first limitation of "*determining whether a specific interaction between said first and second molecule had occurred*".

d. The term "specific interaction" of claim 1 is a relative term, which renders the claim indefinite. The term "specific interaction" is not defined by the claim, the

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

e. The Claim 17 is vague and indefinite because its limitation of "*wherein step (c) is effected in (micro-) array format, preferably on a membrane and/or filter and/or a glass slide and/or in a microtiter plate*" is synonymous to the limitation of Claim 1 step (d) of "*wherein steps (a), (b) and (c) are carried out in parallel in one or more containers, preferably representing an arrayed form*"

2. Claim 13 recites the limitation "second molecule target" in line 1. There is insufficient antecedent basis for this limitation in the claim 1.

3. Claims 1-2, 4-5, 10-17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The step(s) of "selecting" a member of a number of specifically interacting molecules from libraries.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-5, 10-13, 15-17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by M^{c}Connell et al. (*Biotechniques*, **2/1999**, 26(2):208-214).

M^{c}Connell et al. disclosed several different methods for screening phage display libraries (pg. 208, left col., lines 1-8). One method of screening uses the paramagnetic beads wherein the target antibody (second molecule) is immobilized (pg. 208, left col., line 40 to pg. 214, left col., line 18). The method step comprise of a) reacting the phage (first molecule) of a phage libraries to the target antibody (refers to step (a) of Claim 1), b) washing the paramagnetic beads (refers to step (b) of Claim 1), c) determining the antibody-binding phage (pg. 208, middle col., lines 1-6) (refers to step (c) of Claim 1), d) selecting the binding phage (pg. 211 (middle page), middle col., line 18 to right col., line 7) (refers to step (d) of Claim 1). The determination step is performed by plague lifts with nitrocellulose filters (pg. 211 (middle page), right col., lines 8-19) (refer to Claims 15-17). The methods further comprise of sequence analysis of the binding phage (pg. 214, left col., line 46 to middle col., line 4) (refers to Claim12). Thus the method of M^{c}Connell et al. anticipates the presently claimed method.

6. Claims 1-2, 10-13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kausch et al. (US Patent 5,508,164).

Kausch et al. disclose a method of separating and isolating biological material using magnetic particles (col. 5, lines 9-20). The method steps comprise of immobilizing the biological material such as polypeptides (second molecule) to a support such magnetic particle,

binding the biological material to a binding composition such as antibody (first molecule) (refers to step (a)), the biological material-binding composition complex is wash with a buffer (refers to step (b), the polypeptides are isolated by magnetic immunoprecipitation (refers to step (c)), and the polypeptides are sorted by a magnetic field (refers to step (d)). Therefore, the method of Kausch et al. anticipates the presently claimed method.

7. Claims 1-2, 4, 10-13, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chagnon et al. (US Patent 4,628,037).

Chagnon et al. disclose several different binding assay using magnetic particles (col. 8, line 65 to col. 9, line 2; col. 15, line 3 to col. 17, line 58). One type of binding assay is the affinity chromatography wherein the method steps comprise of reacting the ligate such as polysaccharides (first molecule) to the ligand such as antibody (second molecule), which is coupled to magnetic particle (refers to step (a)), the magnetic particle with the bound ligate is separated and washed (refers to step (b) and (c)), The ligate is recovered by desorption (refers to step (d)). Therefore, the method of Chagnon et al. anticipates the presently claimed method.

8. Claims 1-2, 10-17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Neurath et al. (US Patent 5,798,206).

Neurath et al. disclosed a method of screening of a test compound for inhibiting the binding of a receptor (col. 2, lines 9-12). The method steps comprise of (a) preparing a magnetic ligand by mixing a magnetic, CD4-containing substrate with HIV-1, (b) mixing the magnetic ligand from step (a) with a test compound, (c) adding cells that express the HIV-1 second

receptors to the mixture from step (b), (d) separating cells with bound magnetic ligands from cells without bound ligands by contact with a magnetic separator, and (e) quantifying the cells with bound magnetic ligands and quantifying the cells without bound magnetic ligands. The magnetic separator preferably comprises permanent magnets enclosed in a plastic frame, which can accommodate 96-well plates. Therefore, the method of Neurath et al. anticipates the presently claimed method.

9. Claims 1-2, 4-5, 10-17, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al. (US Patent 5,922,617).

Wang et al. discloses a method for screening a large numbers of components, wherein either first component or second component is bound to a solid substrate, where one is interested in the determining the interaction between the first and second components (col. 1, line 66 to col. 2, line 4; col. 17, lines 56-67). The method comprises of reacting the bound component (second molecule) with the mobile component (first molecule) (refer to step (a)) (col. 9, lines 56-59), washing the solid substrate (refer to step (b)) (col. 9, lines 61-64), and determine the interaction between the two components (refers to step (c)) (col. 10, lines 7-9) (col. 9, line 26 to col. 10, line 19). Additionally, the method comprise of arranging the solid substrate onto a support (container) in a predetermine pattern (array form) (refers to step (d)) (col. 6, lines 36-45). The solid substrate include magnetic bead (col. 5, lines 60-64). The bound components include nucleic acids and proteins (col. 3, lines 46-61; col. 5, lines 7-10). The bound component is either directly or indirectly (e.g. covalent or non-covalent binding) bound to the solid substrate (col. 3, lines 12-36) (refers to claim 13).

The features of remaining dependent claims are either specifically described by the reference, are inherently present in the method (e.g. the characterization of the first and second molecules), or constitute obvious variations in parameters which are routinely modified in the art (e.g. . the type of immunological means and the type of container), and which have not been described as critical to the practice of the invention.

Thus the method of Wang et al. anticipates the presently claimed method.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
February 4, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER